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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,257	11/05/1999	PAUL A. CLEMONS	385A-US	4970

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EXAMINER

PARAS JR., PETER

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 09/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/435,257

Applicant(s)

CLEMONS ET AL.

Examiner

Peter Paras, Jr.

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 21 August 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: 12-18,22,24,25,27,29-31,33,35,37,39 and 51.

Claim(s) rejected: 1-11,20,21,23,26,28,30,32,34,36 and 38.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☒ The proposed drawing correction filed on 21 August 2003 is a) ☒ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 2. NOTE: Although the proposed amendment to claim 12 would correct the improper multiple dependency, entry of the proposed amendment would require additional searching and/or further action as the improper multiple dependent claims were previously withdrawn from consideration. It is noted that 51 as written is still improperly multiply dependent. See the final office action.

Continuation of 5. does NOT place the application in condition for allowance because: the proposed amendments to the claims have not overcome the rejections of record. The rejection of claim 28 under 35 U.S.C. 101 is maintained as the claim was not amended and the rejection was not addressed. The rejection of claims 26, 28, 30, 32, 34 and 38 under 35 U.S.C. 112, 1st paragraph is maintained. Applicant's arguments have been fully considered but are not found persuasive. Applicants continue to argue that methods of creating transgenic non-human animals are known in the art and that U.S. patents directed to transgenic non-human animals have issued. In response, the Examiner maintains that the transgenic art is unpredictable with respect to transgene expression and the phenotype resulting from transgene expression. See pages 5-6 of the final office action. Applicants have not addressed this point. The rejection of claims 26, 30, 34, 36, and 38 under 35 U.S.C. 112, 1st paragraph is maintained. Applicant's arguments have been fully considered but are not found persuasive. Applicants have argued that many US patents containing claims to genetically engineered host cells have issued. Applicants assert that claim 30 should not have been included in the instant rejection. Applicants assert that genes have been transferred in vivo into a variety of organisms. The Examiner maintains that the evidence of record has not provided guidance that correlates expression of a nucleotide sequence encoding a CAB domain in a cell in vivo with any particular effect. It is further maintained that the art of gene therapy is unpredictable. See pages 7-8 of the final Office action. Claim 30 was properly included in the rejection because the claim can be interpreted to read on a cell in vivo. The term encapsulated does not exclusively imply isolated, it can simply mean surrounded by a membranous envelope, which can be interpreted to mean a cell membrane or even skin in the context of a whole organism. The term biocompatible simply means compatible with living tissue. The rejection under 35 U.S.C. 112, 2nd paragraph is maintained. Applicants argue the GenBank accession numbers were part of the original disclosure. Applicants argue that the sequences of Cal A and Cal B were well known in the art. In response, the Examiner asserts that the sequences presented in the GenBank accessions are directed to nucleotide sequences and do not appear to distinguish which bases correspond to the recited peptide fragments in the claims. It is maintained that there is no uniform numbering system amino acids known in the art. It is further maintained that the specification has not provided a sequence for either Cal A or Cal B. MPEP 608.01(p) states that essential material may not be incorporated by reference to non-patent publications. GenBank accessions are considered non-patent publications. The rejection of claims 1-4, 11, 20-21, 26, 28, 34 and 36 as being anticipated by Guerini et al is maintained. Applicants argue that the claims recite functional language that is not disclosed in Guerini. In particular, Applicants point out that Guerini does not discuss formation of a tripartite complex. In response, the Examiner asserts that as set forth in the previous Office action on page 10, Guerini anticipates the sequences embraced by the claims. The formation of a tripartite complex appears to be an inherent property of the sequences. Since Guerini anticipates the sequences then Guerini has inherently anticipated the functional limitation of formation of a tripartite complex. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spade, 911F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See the M.P.E.P. 2112.01. Applicants have not provided evidence as to why a tripartite complex would not form with the sequences of Guerini. The rejection of claims 1, 5-11, 20, 23, 26, 28, 34 and 36 as being unpatentable over Guerini or Guerini taken with Chaudhuri and Crabtree is maintained. Applicants have argued that the combination of references does teach formation of a tripartite complex. In response, the Examiner asserts that formation of a tripartite complex appears to be an inherent property of the sequences as discussed above. Accordingly, all of the previous rejections are maintained for the reasons of record.

PETER PARAS  
PATENT EXAMINER

